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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/027,248	12/21/2001	Gregory P. Kushla	BAI-007CPACN	9410

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EXAMINER	
TRAN, SUSAN T	

ART UNIT	PAPER NUMBER
1615	9

DATE MAILED: 05/28/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/027,248	KUSHLA ET AL.	
	Examiner	Art Unit	
	Susan Tran	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 March 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *8* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Receipt is acknowledged of applicant's Information Disclosure Statement filed 12/02/02, Request for The Extension of Time and Amendment filed 03/24/03.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on 12/02/02 was filed after the mailing date of the Office Action on 09/24/02. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3 are rejected under 35 U.S.C. 102(b) as being anticipated by Lomen EP 0 068 838 A1.

Lomen teaches a composition comprising combination of narcotic analgesic and ibuprofen or flurbiprofen (see abstract). The composition can be prepared in powder, granule, tablet or capsule oral dosage form (page 2, lines 24-30). The oral dosage form further comprises diluent, lubricant, and binder (page 2, lines 31 through page 3, lines 1-20).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 4-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lomen EP 0 068 838 A1, and Haas US 4,859,704.

Lomen is relied upon for the reason stated above. Lomen does not teach the claimed filler, lubricant, and disintegrant agents.

Haas teaches a composition comprising ibuprofen in conjunction or combination with other medications such as narcotics (column 1, lines 15-27). Haas also teaches the use of silicon dioxide, binder, sodium starch glycolate, lubricant, and filler in an oral dosage tablet (example 2). Haas is silent as to the claimed amount of silicon dioxide, however, generally, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Thus, it would have been obvious for one of ordinary skill in the art to prepare the oral dosage form of Lomen using the excipients and carriers taught by Haas, because the references teach the advantageous results in the use of solid dosage form comprising

combination of ibuprofen and narcotic with known oral dosage carrier useful in pharmaceutical art.

Claims 4-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lomen EP 0 068 838 A1, and Elger et al. US 4,844,907.

Lomen is relied upon for the reasons stated above. The reference is silent as to the teachings of the claimed filler, lubricant, and disintegrant agents.

Elger teaches tablet composition comprising combination ibuprofen and narcotic analgesic (abstract and examples). Elger teaches tablet composition can be made by wet granulating the active ingredients and excipients, including microcrystalline cellulose, starch, binder, glidants, anti-adherents, and disintegrants (columns 3-5). Thus, it would have been obvious for one of ordinary skill in the art to prepare the oral dosage form of Lomen using the excipients and carriers taught by Elger, because the references teach the advantageous results in the use of solid dosage form comprising combination of ibuprofen and narcotic with known oral dosage carrier useful in pharmaceutical art.

The examiner notes that Elger does not teach the amounts of actives, excipients and relative proportions of the granule and extra granule material. However, it is the position of the examiner that no criticality is seen in the particular limitations since the prior art obtains the same result desired by the applicant, *e.g.*, compressed tablet having good stability, disintegration times and dissolution rates. Thus, it would have been obvious for one of ordinary skill in the art to, by routine experimentation determine

suitable amounts of actives and excipients to obtain at least similar result, because Elger teaches the advantageous results in using the same ingredients.

Response to Arguments

Applicant's arguments filed 03/24/03 have been fully considered but they are not persuasive.

Applicant argues that Elger does not teach compositions comprise extra-granule material or colloidal silicon dioxide. However, the broad term "extra-granule material" permits materials, such as binder, lubricant, carrier, and excipient. Colloidal silicon dioxide is a well-known glidant/lubricant in pharmaceutical art, and therefore, it would have been obvious to the skilled artisan to, by routine experimentation select colloidal silicon dioxide as a glidant in view of the teaching of Elger.

Applicant argues that Elger does not teach ibuprofen and narcotic in one phase, and therefore would not have been obvious to combine. In response to applicant's argument, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981). It is further noted that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either

in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988)and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, Elger is relied upon for the teachings of the well-known excipients and carriers in an oral solid dosage form.

Pertinent Arts

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Cooper et al., McGivney et al., Ferrer-Brechner et al., and Lomen are being cited as for the teachings of ibuprofen in combination of other analgesic.

Conclusion

Applicant's submission of an information disclosure statement under 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p) on 12/02/02 prompted the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 609(B)(2)(i). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600